

New claims 42-49 have been added. These claims are specifically directed to devices of the present invention for the detection of hydrogen peroxide plasma.

Claim 1 has been restricted to plasma. This amendment, it is submitted takes the claim out of the scope of the disclosure of Ignacio, even though, as pointed out below, plasma is mentioned in that specification

Applicant respectfully traverses the rejection of claims 1-21,24,27-41 under 35 USC 102(e) over Ignacio.

Applicant has carefully studied the points made by the Examiner with respect to Ignacio and does not traverse the facts the examiner sets forth. However it is applicant's position that this exposition, while it addresses many similarities does not address the critical differences between the two inventions. Two of these relate to plasma and paper.

It should be pointed out that plasma is a state of matter which is quite different from that of vapor derived from the same substrate. Thus a device which is suitable for testing for liquid peracid or vapor thereof, does not suggest its utility in testing for plasma. Plasma is an extremely reactive state of matter, far more so than its liquid or vapor state. At column 5 line 55, Ignacio does indeed mention plasma in passing. There is no further reference to plasma in their text. This is not surprising as one skilled in the art who tried to apply the Ignacio teaching to plasma detection would fail if plasma was actually present. Not only that, but use of paper in a test device for plasma, will automatically turn the device off (see below). The reason for this is that contrary to the device of applicant which uses a polymeric substrate, Ignacio uses paper as a substrate. It is well accepted in the art that plasma will burn up paper very rapidly.

In support of this position there is enclosed herewith a copy of Department of Defense publication entitled: "*Low temperature oxidative sterilization methods for sterilizing medical devices*".

On the first page, second paragraph, the methodology for creation of hydrogen peroxide plasma is set forth. As will be seen, plasma is ionically charged. Thus plasma will NOT work in the Ignacio device not only because of the paper problem, but it would be discharged by the barrier film which is a critical part of this device. Such a barrier, of course, is absent from applicant's device.

On the second and third pages incompatibility with cellulosic materials such as paper is mentioned.

There are yet further differences which take the present invention out of any shadow of 35 USC 102 as well as 103 based on Ignacio.

The color change in the reference appears to be based on halogenation. This of course is a totally different chemical reaction from hydrohalogenation which is the basis

of the color change in the present invention. By no stretch of the imagination does one teach, or even suggest the other.

The device of the present invention permits direct contact with the material being tested, ie the plasma. Furthermore, unless the "wedge" modification is being used, in the present invention, the color change is uniform across the entire test strip. In the reference, the color change spreads from one edge to the center.

Presumably because of the nature of the materials being tested in the reference, a "vapor head space" and a barrier film are critical to its success. These are both absent in applicant's device.

Applicant's device is quite simple, while the reference device is substantially more complex.


Hence the alleged teaching of the present invention by Ignacio is in fact a false lead. Ignacio should therefore be withdrawn is a reference and the rejection falls.

In view of the clear inapplicability of Ignacio, there is no need to discuss the relevance or otherwise of Sato.

In view of the foregoing, it would appear that there is no tenable ground for rejection of any of the claims in the present application, and their prompt passage to issue is respectfully solicited.

This is to certify that the foregoing paper and authorization to charge credit card were transmitted by telefax to the Commissioner for Patents at 703 872 9306 on June 7<sup>th</sup> 2004

Respectfully submitted,

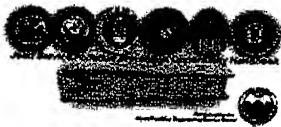


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## LOW-TEMPERATURE OXIDATIVE STERILIZATION METHODS FOR STERILIZING MEDICAL DEVICES



**Revision Date:**  
1/03

**Process Code:**  
Navy/Marines: MD-01-01; Air Force: MD01; Army: N/A

**Usage:**  
Navy: Medium; Marines: Medium;  
Army: Medium; Air Force: Medium

**Compliance Impact:**  
Low

**Alternative For:**  
Ethylene oxide sterilization

**Applicable EPCRA Targeted Constituents:** Ethylene Oxide (CAS: 75-21-8)

### Overview:

Low-temperature oxidative sterilization for medical devices and surgical instruments is a safe alternative to ethylene oxide (EtO) sterilization. Two of these low-temperature oxidative methods include hydrogen peroxide plasma sterilization, developed by Advanced Sterilization Products (ASP) and marketed under the trade name STERRAD™, and peracetic acid gas/plasma technology, developed by Abtox, Inc. and marketed under the trade name PLAZLYTE™. Abtox, Inc. has not received FDA approval for its technology and is not sold in the U.S.

Hydrogen peroxide plasma sterilization uses 1.8 milliliters of 58 percent hydrogen peroxide that is vaporized in a sterilization chamber. The vapor is converted into a plasma through the use of radio frequency (RF) energy.<sup>1</sup> The plasma consists of highly charged particles and free radicals to sterilize instruments in about one hour without producing toxic residues or emissions. The only byproducts of this method are water vapor and oxygen.

Peracetic acid gas/plasma technology provides a continuous infusion of peracetic acid gas into the sterilization chamber, where the gas is subjected to RF energy and converted to a plasma state.<sup>2</sup> Peracetic acid plasma technology requires a cycle time of about three hours.

Hydrogen peroxide plasma sterilization and peracetic acid gas/plasma sterilization will have the greatest impact in the smaller volume areas, such as in-hospital sterilization. According to one study,<sup>3</sup> both methods are emerging technologies and are unable to handle large-volume requirements; therefore, they will not greatly affect the industrial sterilization market in the next few years.

<sup>1</sup> CDR T.C. Stewart, Head, Sterile Processing, National Naval

Medical Center, Bethesda, Maryland, 20889-5000, "Sterilization Alternatives to Ethylene Oxide."

<sup>2</sup> Stewart.

<sup>3</sup> Michael H. Scholla and Mary E. Wells, "Tracking Trends in Industrial Sterilization," *Medical Device & Diagnostic Industry*, September 1997.

**Compliance Benefit:**

Switching to hydrogen peroxide plasma sterilization should decrease the amount of power consumed during the sterilization process. This will help facilities meet the requirements of Executive Order 13123, *Greening the Government Through Efficient Energy Management*. In addition, switching to an alternative sterilization technique (which does not use CFC-12) will help a facility meet the requirements of 40 CFR 82 and EO 13148 requiring Federal agencies to maximize the use of safe alternatives to class I and class II ozone-depleting substances (ODSs). Low-temperature oxidative sterilization methods are currently not subject to the regulatory reporting associated with an emission standard. There is a NESHAP, found at 40 CFR 63, Subpart O, for ethylene oxide emissions from sterilizers that use 1 ton or more of EtO per year, but it does not apply to hospitals or medical facilities.

The compliance benefits listed here are only meant to be used as a general guideline and are not meant to be strictly interpreted. Actual compliance benefits will vary depending on the factors involved, e.g., the amount of workload involved.

**Materials Compatibility:**

*Certain materials (e.g., cellulose products, cotton, paper, towels, certain packaging materials, muslin, dressings, organic materials, water and wadding) are not compatible with hydrogen peroxide plasma units. For example, cellulosic materials will absorb the sterilant, often leading to incomplete sterilization of the device<sup>4</sup>. Materials incompatibility issues for peracetic acid plasma sterilization are unknown.*

<sup>4</sup> Scholla and Wells.

<sup>4</sup> *Tracking Trends in Industrial Sterilization*, Michael H. Scholla and Mary E. Wells, *Medical Device & Diagnostic Industry*, September 1997.

**Safety and Health:**

In hydrogen peroxide plasma sterilization, the hydrogen peroxide used in the process is contained in cassettes or cartridges. At no time does the operator come in contact with the chemical. Also, the process does not produce any toxic residues or emissions. The only byproducts are water vapor and oxygen.

These new technologies minimize the use of the EtO sterilization process. EtO is highly explosive in nature, a known carcinogen/mutagen, and in the sterilization process, must be mixed with a carrier agent such as chlorofluorocarbon (CFC)-12 (Freon®), which is an ODS. Note\*\* Not all instruments are FDA certified for plasma sterilization.

Consult your local industrial health specialist, your local health and safety personnel, and the appropriate material safety data sheet (MSDS) prior to implementing these technologies.

**Benefits:**

A hydrogen peroxide plasma sterilization unit:

- Consumes less power than traditional EtO sterilization units.
- Requires no water, drainage, or venting
- Has shorter cycle times than traditional EtO sterilization units (74 minutes vs. 12 hours)
- Eliminates the use of EtO, a carcinogen/mutagen and highly explosive chemical
- Has significantly lower annual operating costs than traditional EtO sterilization units
- Eliminates the use of CFC-12, an ODS
- Avoids costs and regulatory paperwork associated with the emissions.

**Disadvantages:** Hydrogen peroxide plasma sterilization units:

- *Are not compatible with cellulose products, cotton, paper, towels, certain packaging materials, dressings, and wadding;*
- Are more expensive than EtO sterilization units (\$100,000 vs. \$40,000 for an EtO sterilization unit with the same sterilization volume); and
- Are unable to handle large-volume requirements (i.e., hydrogen peroxide sterilization units can handle the sterilization of items up to about 18 inches; however, larger hydrogen peroxide sterilization units that will be able to meet industrial sterilization requirements are beginning to enter the market).

**Economic Analysis:**

The following cost elements compare the hydrogen peroxide plasma unit to the EtO sterilization unit.

Wilford Hall Medical Center, Lackland Air Force Base in San Antonio, Texas, switched its EtO sterilization unit to a hydrogen peroxide plasma unit in January 1998. A cost analysis was performed in November 1995 by ASP, the vendor of the STERRAD™ unit, and is summarized below.

**Assumptions:**

- Sterilization unit: STERRAD™ 100 Sterilizer
- Sterilization volume: 14,976 cubic ft.
- Supplies: Pouches and wrap, biological indicators, chemical indicators, and tape
- Utilities: EtO sterilization (electricity, steam, and water), hydrogen

peroxide plasma sterilization (electricity)

- EtO tanks: 104 tanks required per year
- Hydrogen peroxide cassettes: \$7.95 per cycle and 4680 cycles per year
- Maintenance and service: Maintenance and service for the hydrogen peroxide plasma units for the first year are included in the capital and installation costs and will be \$17,260 every year thereafter
- Risk management cost: Includes insurance premium, potential employee lawsuits, environmental lawsuits

**Table 1. Cost Comparison for Ethylene Oxide Sterilization vs. Hydrogen Peroxide Plasma Sterilization**

EtO Sterilization

Hydrogen Peroxide Plasma Sterilization

**Capital and Installation Costs:**

Sterilization unit cost, including installation and initial supplies. This cost also includes the 1<sup>st</sup> year maintenance contract for the STERRAD™ unit only:  
\$40,000  
\$100,000

**Operational Costs (1<sup>st</sup> year):**

Supplies:  
\$28,521  
\$28,040

Utilities:  
\$6,627  
\$468

EtO tanks:  
\$63,440  
\$0

Hydrogen peroxide cassettes:  
\$0  
\$37,208

Maintenance, service:  
\$16,000  
\$0

Training, protective attire:  
\$2,000  
\$0

EIO recovery cost:  
\$10,000  
\$0

Risk management cost:  
\$5,000  
\$0

**Total Costs:** (not including capital and installation costs)  
\$131,588  
\$65,714

**Total Income:**  
\$0  
\$0

**Annual Benefit:**  
-\$131,588  
-\$65,714

**Economic Analysis Summary:**

Annual savings for hydrogen peroxide plasma sterilization: \$65,874  
Capital Cost for Equipment/Process: \$100,000  
Payback Period for Investment in Equipment/Process: 1.5 years

[Click Here](#) to view an Active Spreadsheet for this Economic Analysis and Enter Your Own Values. To return from the Active Spreadsheet, click the **reverse arrow** in the Tool Bar.

**Approving  
Authority:**

Appropriate authority for making process changes should always be sought and obtained prior to procuring or implementing any of the technology identified herein.

**NSN/MSDS:**

**Product**  
**NSN**  
**Unit Size**  
**Cost**  
**MSDS\***

STERRAD sterilizer  
None identified  
N/A  
\$N/A

PLAZLYTE sterilizer  
None Identified

N/A  
\$N/A

*\*There are multiple MSDSs for most NSNs.  
The MSDS (if shown above) is only meant to serve as an example.*

**Points of Contact:**

**Air Force:**  
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**Navy:**  
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DSN: 253-5546  
FAX: (757) 444-7261  
E-mail: [rogersw@nehc.med.navy.mil](mailto:rogersw@nehc.med.navy.mil)

**Vendors:**

This is not meant to be a complete list, as there may be other manufacturers of this type of equipment.

Advanced Sterilization Products  
A Division of Johnson & Johnson Medical, Inc.  
33 Technology Drive  
Irvine, CA 92618  
Phone: (800) 595-0200 or (949) 450-6800  
FAX: (949) 450-6800  
E-mail: [aspcomment@aspus.ini.com](mailto:aspcomment@aspus.ini.com)  
Sales & Technical:  
Phone: (888) 783-7723 or (949) 453-6400

AbTox, Inc.  
104 Terrace Drive  
Mundelein, IL 60060-3826  
Phone: (800) 228-6950 or (847) 949-0552  
**Note:** \*\*PlazLyte is not currently sold in the US

**Sources:**

Sgt. Ernest Nichols, Wilford Hall Medical Center, December 1999.  
Conversation with Mr. Bill Rogers, BUMED Environmental Program Manager, Navy Environmental Health Center, March 6, 1998.  
Conversation with Captain DeDecker, Wilford Hall Medical Center, March 8, 1998.  
Sterilization Alternatives to Ethylene Oxide, CDR T.C. Stewart, Head, Sterile Processing, National



Naval Medical Center, Bethesda, Maryland.

~~Trachoma is a disease of the eye caused by the bacterium Chlamydia trachomatis. It is a leading cause of blindness in the world. The disease is caused by a bacterium that is spread by contact with infected secretions. The disease is most common in children and young adults. It is a leading cause of blindness in the world. The disease is caused by a bacterium that is spread by contact with infected secretions. The disease is most common in children and young adults.~~

Vendor information from Advanced Sterilization Products (ASP), a division of Johnson & Johnson and AbTox, Inc.